Assessment of the HIV/AIDS Medical Supplies and Laboratory Commodities Supply Chain in Lesotho, November 2007

February 2009
This report was made possible through support provided by the U.S. Agency for International Development, under the terms of cooperative agreement number HRN-A-00-00-00016-00. The opinions expressed herein are those of the author(s) and do not necessarily reflect the views of the U.S. Agency for International Development.

About RPM Plus

RPM Plus works in more than 20 developing and transitional countries to provide technical assistance to strengthen pharmaceutical and health commodity management systems. The program offers technical guidance and assists in strategy development and program implementation both in improving the availability of health commodities—pharmaceuticals, vaccines, supplies, and basic medical equipment—of assured quality for maternal and child health, HIV/AIDS, infectious diseases, and family planning and in promoting the appropriate use of health commodities in the public and private sectors.

About SCMS

The Supply Chain Management System (SCMS) was established to enable the unprecedented scale-up of HIV/AIDS prevention, care and treatment programs in the developing world. SCMS procures and distributes essential medicines and health supplies, works to strengthen existing supply chains in the field, and facilitates collaboration and the exchange of information among key donors and other service providers. SCMS is an international team of 16 organizations funded by the U.S. President’s Emergency Plan for AIDS Relief (PEPFAR). The project is managed by the U.S. Agency for International Development.

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<td>essential medicines list</td>
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<td>fixed-dose combination</td>
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<td>Millennium Challenge Corporation</td>
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<td>OI</td>
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ACKNOWLEDGMENTS

Key to the success of this assessment was the accessibility and cooperation of the various units of the Ministry of Health and Social Welfare and the health facilities which selflessly allowed their own important tasks to be interrupted as they gave assistance to members of the assessment team. In particular, the assistance of the management and staff of the Pharmaceutical and Laboratory Services Directorates in the sampling of sites and actual data collection was invaluable and is acknowledged with thanks.

Equally vital was the cooperation of the members and staff of all the stakeholders who assisted the assessment by agreeing to be interviewed, making valuable comment on key issues and making available relevant documentation.

Sincere appreciation is due to the U. S. Government PEPFAR Team in Lesotho for taking the fight against the scourge of HIV/AIDS in this country further by supporting this assessment. Thanks also go to the respective U. S. Agency for International Development cognizant technical officers based in Washington, D.C., for supporting this joint assessment.

Last, but by no means least, the members of the assessment team acknowledge the support of their colleagues from their respective organizations who participated in the planning and logistics for the assessment.
Figure 1. Map of Lesotho
EXECUTIVE SUMMARY

In 2007, the Lesotho U. S. President’s Emergency Plan for AIDS Relief (PEPFAR) team requested the Supply Chain Management System (SCMS) and Rational Pharmaceutical Management (RPM) Plus programs to undertake a comprehensive analysis of the HIV/AIDS and other related commodities supply chains in Lesotho. This request followed widespread reports of shortages at facility level of essential HIV/AIDS-related commodities including antiretroviral (ARV) medicines, laboratory reagents, disposable supplies, rapid test kits, and condoms. Program managers had also expressed concern that the procurement and distribution of HIV/AIDS commodities was fragmented and uncoordinated.

The assessment’s objectives were to conduct a desktop review of supply chain management in Lesotho and perform an in-country assessment to address gaps identified. Activities were to include meetings with government officials, service providers, and other stakeholders; field visits; a review of processes around the management of ARVs and related commodities; mapping ARV supply chain activities and related commodities; and identification of the strengths and weaknesses of the HIV/AIDS supply chain in Lesotho. The resulting report would be considered by the Ministry of Health and Social Welfare (MoHSW) and in-country partners and donors, and would take into account the severe crisis in health human resources that exists currently in Lesotho and the multiplicity of partners involved in procurement and supply chain systems.

Pharmaceutical and Laboratory Services: Findings and Recommendations

Key Findings—

- There is effectively no legislative control over general medicines as the existing tool is obsolete. The Medicines Control Bill, which will establish the Medicines Regulatory Authority, has been submitted to the Ministry of Parliamentary Affairs for drafting.

- Despite the existence of training institutions for pharmacists and pharmacy technicians, the severe staff shortage has persisted, as at the time of the report there were no posts to absorb the output of the training institution

- A number of vertical programs are involved at the different levels of the medicines supply chain for ARVs and other HIV/AIDS commodities within the MoHSW. These remain uncoordinated in terms of funds and supply chain activities.

- The National Pharmacy and Therapeutics Committee (NPTC) which is responsible for selecting an essential medicines list (EML) and developing standard treatment guidelines (STGs), is not yet in place, although the Pharmaceutical Directorate is facilitating efforts to establish the NPTC. The current EML and STG (finalized in 2006) that have just been released are already due for review.
• The NDSO, responsible for the procurement, storage, and distribution of pharmaceuticals, is now overloaded with an increasing volume of donated commodities, particularly ARVs and opportunistic infections (OIs) and, recently, laboratory supplies. This has created a burden for NDSO, as it is also barely coping with the resultant increase in operational costs which it currently absorbs.

• Most facilities were found to have over 80 percent of basic ARVs in stock, although inventory management continues to be a problem. This situation is due largely to a lack of or insufficient supervision which, in turn, is caused by low staffing levels.

• The National Lesotho Laboratory Service (NLLS) has no laboratory policy or national strategic laboratory plan in place, and thus no coordinated strategy to address the problems of laboratory tests related to HIV/AIDS and tuberculosis (TB).

• All assessed hospitals had qualified technologists and technicians, but not adequate numbers—HIV testing is being performed by lay counselors in the health centers.

• The laboratories assessed appeared to have adequate funds for laboratory commodities, but no control over funds generated from the tests.

• Logistics is a serious problem in the laboratory services, with no logistics management information system (LMIS) in place and few of the laboratories using stock cards. The placing of orders was found to be erratic and inconsistent and less than 50 percent of the laboratories sent stock reports to the district or central levels.

• The laboratories were generally well-stocked and had service contracts with suppliers, but infrastructure can be improved.

Key Recommendations

The following key recommendations were made—

• Fast-track the drafting and final adoption of the Medicines Control Bill to pave the way for the establishment of the medicines regulatory authority

• Establish a pharmaceutical technical committee to coordinate partner efforts and activities to ensure improved service delivery

• Create district and hospital posts for pharmacists and pharmacy technicians once the new organogram has been approved

• Create mechanisms to ensure that NDSO, the HIV/AIDS, and the Pharmacy Directorate work closely in matters related to budget, procurement, storage, and distribution of ARVs and related commodities
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- Make establishment of the NPTC a priority during the current year
- Investigate the feasibility of an administration fee for NDSO for donor-funded commodities to meet storage and distribution costs; implement a sustainable warehouse management information system and prepare a laboratory commodities procurement plan
- Develop a national laboratory policy and strategic plan and develop and implement SOPs for the various laboratory activities
- Design a national logistics system for laboratory services
- Review staffing levels for laboratory services in accordance with the human resources plan, current workload, and test profiles performed at each level of care
- Ensure that the necessary laboratory expertise support is available to NDSO before they take over procurement, storage and distribution of all laboratory commodities

Development Partners and Coordination Efforts

Development partners play a vital role in the fight against HIV/AIDS in Lesotho. However, coordination and communication between government departments and donors—and among the donors themselves—was neither streamlined nor consistent. The following recommendations were made to address the findings of the report—

- Define and communicate clearly the MoHSW central mandate for coordination of national supply chain management activities
- Circulate this report among the development partners; invite each to indicate areas of interest and to make proposals around coordination of effort
- Consider the formation or revival of a logistics subcommittee for the coordination of the logistics management of HIV-related medicines and laboratory commodities, with clear terms of reference
- Consider the establishment of an active donor coordination desk which would be visible to all partners and have sufficient clout within the MoHSW

It is hoped that the findings of this report and consideration and implementation of the recommendations will have a positive effect on the availability of HIV/AIDS and TB-related medicines and laboratory commodities in Lesotho to the ultimate benefit of the people of the country.\^{1}

\(^{1}\) A donor coordinating committee has been established in the Ministry of Health under the auspices of the DGHS since the beginning of the assessment.
Proposed MSH/SPS Support Activities for the Pharmaceutical and Laboratory Sectors

SPS has identified a number of activities, some continuing from the previous financial year, others new and resulting directly from the findings of the assessment, that have now been incorporated into its Lesotho Country Operational Plan (COP), for 2009 which is available on request.

Proposed Support Activities for the Pharmaceutical Sector

The Management Sciences for Health (MSH) Strengthening Pharmaceutical Systems (SPS) program, the RPM Plus follow-on, continues to support the following areas—

- Reviewing existing pharmaceutical regulation and legislation
- Establishing the planned medicines regulatory authority and related training of its staff and officials
- Training health personnel (with focus on pharmacy personnel) in drug (and other commodities) supply management, quantification of requirements, HIV/AIDS management, TB management, Pharmacy Therapeutics Committees (PTC), and infection control
- Review of the NEDL and STGs
- Monitoring and evaluation of the availability of essential commodities
- Implementing computerized and manual systems at NDSO and health facilities

Proposed Support Activities for the Laboratory Sector

It is envisaged that most of the activities described below will commence in the middle of financial year 2009. PEPFAR funding has already been applied for. In the main, the activities in this sector can be summarized as follows—

- Seek collaboration with all other partners providing support to the laboratory services and propagate for the formation of a laboratory coordinating committee
- Appoint a full-time laboratory commodity management specialist in Lesotho to oversee all laboratory commodity management support activities and build capacity
- Train laboratory staff in all the laboratories and the blood transfusion center in the use of stock cards, quarterly stock taking, and quarterly logistics reports
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- Assist laboratory staff to organize refrigerated storage in individual laboratories
- Assist with development of the national standard list of essential laboratory commodities required to carry out the tests needed at each level of the health system
- Use the national list of essential laboratory commodities to assist with the development and dissemination of a national laboratory stores catalogue;
- Develop a national laboratory inventory management system based on consumption data which provides for (1) national quantification required for procurement, and (2) quantification to identify how much to distribute to each individual laboratory
- Institute a monitoring and evaluation system for commodity management (checks and balances, audit), train staff in its use, and provide ongoing support
- Provide ongoing support in laboratory logistics management, tendering, and procurement
INTRODUCTION AND BACKGROUND

Background to the Assessment

Despite the interventions of donors and technical organizations, such as the U.S. President’s Emergency Plan for AIDS Relief (PEPFAR), Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM), World Bank, World Health Organization (WHO), Clinton Foundation, and other HIV/AIDS-related initiatives in Lesotho, shortages of essential HIV/AIDS-related commodities including ARV medicines, laboratory reagents, disposable supplies, rapid test kits, and condoms, have been widely reported. Moreover, program managers have recognized that HIV/AIDS commodity procurement is fragmented and uncoordinated.

Two organizations have focused their efforts in addressing some of above issues.

- Health Research for Action (HERA)—HERA was awarded a World Bank-funded contract to strengthen inventory management and security at all hospitals so that the National Drug Service Organization (NDSO) and the Procurement Unit could conduct procurement using international competitive bidding. This includes the procurement of health sector goods financed through the GFATM.

- Management Sciences for Health (MSH)—In October 2005, the RPM Plus Program, managed by MSH, received funds from the U. S. Agency for International Development (USAID) through the PEPFAR program to strengthen pharmaceutical services and the availability and appropriate use of antiretrovirals and HIV/AIDS-related commodities at the district level.

In 2007, the Lesotho PEPFAR Team requested the Supply Chain Management System (SCMS) and the Rational Pharmaceutical Management (RPM) Plus programs to undertake a comprehensive analysis of the HIV/AIDS and other related commodities supply chains in Lesotho. Funded by PEPFAR, SCMS has been created to operate a safe, secure, reliable, and sustainable supply chain to procure and distribute pharmaceuticals and other commodities needed to provide care and treatment of persons with HIV/AIDS and related infections globally on behalf of the U.S. Government. Both SCMS and RPM Plus are global programs.

Objectives of the Assessment

The objectives of the assessment were to—

- Conduct a desktop review of all available documentation/reports relevant to supply chain management in Lesotho to identify the areas which have not been documented and inform the nature and extent of any information gaps that may still need to be assessed.
• Conduct an in-country assessment to address gaps identified during the desktop review to include—
  
  o Consultative meetings with relevant government officials, service providers, and other stakeholders
  
  o Field visits to a sample of representative facilities
  
  o Review of processes and forms related to the management of HIV and AIDS and related commodities
  
  o Mapping of the procurement, storage and distribution of HIV/AIDS, and related commodities throughout the supply chain

• Identify the strengths and weaknesses of the HIV/AIDS supply chain system in Lesotho

Write a situation analysis report including short-, medium-, and long-term recommendations to be considered by in-country partners and donors taking into account (1) the severe crisis in health human resources currently existing in Lesotho, and (2) the multiple partners that are currently involved in procurement and supply chain systems.

The Lesotho Health System

The Kingdom of Lesotho is a small, mountainous country of about 1.8 million people located in Southern Africa, and entirely surrounded by South Africa. Lesotho is a constitutional monarchy with an elected parliament, and is divided into 10 administrative districts in three zones—north, central, and south. It is the highest country in the world with elevations ranging from about 1,500 meters in the lowlands around the capital, Maseru, to over 3,600 meters in the Maloti/Drakensberg mountains.

The economy of Lesotho is primarily agricultural—much of it subsistence—with some activity in textile and other manufacturing industries. A large share of national income is from remittances from migrant workers in South Africa. Unemployment is, however, high and is estimated to be 40 percent. The high unemployment level is due in part to restructuring of the mining industry in South Africa. Over half of the population in Lesotho lives below the poverty line.

Guided by the country’s development vision as specified in the Vision 2020 of Lesotho, the goal of the National Health Policy (NHP, 2004) is “to have a healthy population, living a quality and productive life by 2020.” The policy’s three main objectives are to—

• Reduce morbidity, mortality, misery, and human suffering

• Reduce inequalities in health and social welfare, and in access to health and social welfare services
• Improve the health status and social welfare of the population for socioeconomic development

The guiding principles of the NHP include the primary health care (PHC) approach of equity, accessibility and availability, affordability, efficient use of resources, and quality. To achieve the largest possible impact on health with the limited available resources, priorities are defined in the District Health Package (DHP), which covers the following basic services—

• Public health interventions (health education, immunization, nutrition, Integrated Management of Childhood Illness, and environmental health)

• Communicable disease control (HIV/AIDS, sexually transmitted infections [STIs], and TB)

• Sexual and reproductive health rights

• Essential clinical services (common illnesses, basic dental care, and mental health services)

The implementation framework for health sector development is laid down in the Health and Social Welfare Strategic Plan 2004/05-2010/11 (March 2004) of the MoHSW with the overall goal being “to contribute to the attainment of improved health status and quality of life for socioeconomic development.” (HERA Inception Report, November 2006)

Lesotho’s health system is organized in three levels—

• The MoHSW and its various operating units at the central level

• Ten District Health Management Teams (DHMTs), which include the hospitals, and three urban filter clinics

• One hundred eighty-five health centers in urban and rural areas

The DHMTs have been recently established in all 10 districts, and are responsible for administering and supervising all primary health centers in their districts. The hospitals and health centers are a legacy of the old colonial district hospitals and the church-affiliated hospitals that serve remote rural populations. When Lesotho gained its independence in 1966, there were only nine districts, each of which had its own hospital in the district center. A tenth district—Thaba Tseka—was created later in the east-central part of the country, but it does not have its own hospital.

The hospitals have a variety of wards and clinics providing emergency and surgical services, maternal and child health, pediatrics, antiretroviral therapy (ART), and other HIV-related services. Each hospital has a pharmacy store and a dispensary. The administration of the DHMT is based in the hospitals. The urban filter clinics are located in Maseru (two) and Maputsoe (one) and staff include at least one doctor. They provide urgent care and maternity services, excluding
surgery, and can admit patients for up to seven days. The health centers provide PHC and are generally staffed by nurse clinicians, public health nurses, and/or nurse midwives.

Another major provider of health care services in Lesotho is the Christian Health Association of Lesotho (CHAL). CHAL is an umbrella organization of different churches that operate hospitals serving remote areas. In terms of ownership, four of the hospitals are owned by the Roman Catholic Church, two by the Lesotho Evangelical Church, and one each by the Seventh Day Adventist and the Anglican Church of Lesotho. The other member churches are the Assemblies of God and the Bible Covenant. CHAL has a Memorandum of Understanding with the Government of Lesotho to provide health services and to administer the health centers in their respective areas. Their facilities are also under the supervision of the DHMTs and the government subsidizes the CHAL facilities by contributing program funds and providing assistance in salary payments to technical staff.

In addition to the government and CHAL facilities, the Lesotho Flying Doctors Service manages a network of health centers that are inaccessible by road. Community-Based Distributors (CBDs) of contraceptives and voluntary testing and counseling staff administer rapid HIV testing door-to-door at homes.

Procurement, storage, and distribution of pharmaceuticals and other health commodities are the responsibility of the NDSO, established as a trading account in a Finance Notice of 2007. NDSO supplies all public sector facilities, the CHAL hospitals, and a few private sector hospitals. In general, NDSO supplies all levels of care through a requisition system in which facilities pull supplies based on their budget allocations. A push system is used for requisitioning of ARV drugs and HIV test kits, including those required for prevention of mother-to-child transmission (PMTCT). Orders and reports are submitted directly to the program office, HIV/AIDS Health Products Coordinating Office (HAHPCO), at the Pharmaceutical Directorate, which determines quantities of re-supply to each facility and provides the requisitions to NDSO for delivery to the health facility.

In the private sector, there are a number of private doctors and pharmacies. Some of the private doctors have formed group practices that operate small hospitals. They are competing directly with similar practices in South Africa, which, given its proximity, is also a major source of private health care for Lesotho citizens who can afford to pay for their health care.

The HIV/AIDS Situation in Lesotho

The HIV/AIDS epidemic has had a devastating impact on Lesotho’s development. It is a mature pattern, with a high case-fatality ratio, large numbers of orphans and vulnerable children, increasing mother-to-child transmission, decreasing life expectancy, and declining productivity. The national economy has been affected and very high demands placed on the health care system.

In 2005, the prevalence of HIV in Lesotho was estimated at 23.2 percent of adult Basotho aged 15 to 49 years, translating to approximately 266,000 adult men and women living with the HIV infection. The prevalence is particularly high in urban areas with levels of 28.8 percent compared
to 21.8 percent in the rural areas, with a considerable variation in prevalence rates by district. HIV prevalence is highest among the 15 to 49 years age bracket and skewed towards women who represent 55 percent of diagnosed cases of HIV, and more among young women than young men of similar age with a percentage of more than 60 percent to less than 30 percent for young males.

The national response to the HIV/AIDS epidemic in Lesotho has consisted of providing educational programs to increase knowledge and awareness; providing such services as condom distribution and STI management; putting ART centers in all public and CHAL health facilities where ARV medicines are made available to the public at highly subsidized rates; treating opportunistic infections; provision of care and support services to those infected; providing nonmedical services such as shelter or food to aid infected individuals and their families and to facilitate the implementation of relevant interventions.

Challenges and gaps have been identified in HIV interventions, under the process of the National Joint Review Programme response to HIV and AIDS undertaken in 2005 (see National HIV and AIDS Strategic Plan 2006-2011). The interventions currently employed were found to be based on limited strategic analysis and mainly directed by the perceived goals and objectives of individual implementing organizations. Furthermore, they had limited national strategic direction and were inadequately coordinated. These factors were aggravated by the generally low technical resources and absence of clear national strategic priorities.

The key challenges in scaling up ART, with regard to treatment, care, and support include—

- Increasing accessibility of treatment, care, and support
- Ensuring that there are adequate technical human resources and infrastructure
- Ensuring effective commodity procurement, storage and distribution systems

In addition, there are also challenges regarding care and monitoring of patients on ARVs for adherence as well as possible resistance to medicines used in the treatment and care of AIDS patients.

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ii Most facilities are still in the process of improving their infrastructure to cater for the increasing numbers of patient attending the ART centers. The inventory management system of commodities, i.e., ARVs and OIs in the ART centers is not uniform from facility to facility, leading to shortages in some facilities and excess stock in others.

iii Pill count is used as an adherence tool and there is still need for training in the use and verification of more reliable adherence tools.
DESKTOP REVIEW FINDINGS

The national response to the HIV/AIDS epidemic in Lesotho was established immediately after the reporting of the first case of AIDS in 1986. Over the years, several policies, plans, and strategies have been developed and put in place to guide the response to the epidemic. Following a review of the national response at the expiry of the 2002-2005 National Strategic Plan, the new five-year plan, the National HIV and AIDS Strategic Plan (2006-2011), was embarked upon. This plan identified the need “to roll out ART and prolong the lives of the infected individuals, as well as to ensure the treatment, care and support as well as the management of opportunistic infections and follow up for adherence during treatment.”

One of the key challenges identified by the five-year plan in scaling up ART is to “increase accessibility of treatment, care, and support, ensuring that there are adequate human, technical, infrastructural resources and effective commodity procurement and distribution systems….”

Despite all the best intentions of the Government of Lesotho (GOL) and its policies, the shortage of human resources has impeded the successful implementation of most policies and strategies intended to scale up ART and increase access to treatment, care, and support.

An assessment of medicines supply management in the country’s hospital facilities that was conducted by HERA in 2006 highlighted the following major findings—

- Guidelines and procedures for medicines supply management that had been in place for many years were either not available or simply not being followed
- Detailed annual forecasts for pharmaceutical supplies with costs were not being prepared, and budgets tended to be based on historical budget figures; consequently, forecasts were not available to NDSO and the MoHSW Pharmaceutical Directorate for procurement planning
- Training plans for pharmaceutical staff were usually not available, and a need for training in medicines supply management issues and the use of information technology was identified
- Technical supervisory support visits by the MoHSW Pharmaceutical Directorate which were considered to be crucial as there were no pharmacists available at the district hospitals, were not taking place

The study concluded that—

- Attempts by hospital staff to improve the situation were severely constrained by staff shortages and a lack of supervisory support and guidance from hospital management and from MoHSW at national level
Accountability was a general area of concern due to inappropriate procedures, documentation and follow-up regarding safeguarding of stocks and use of pharmaceuticals

Monitoring and evaluation of medicines supply management performance was not done at hospital or national levels, and might be partly due to the lack of information management systems (both manual and/or computerized) and appropriate monitoring and evaluation tools

One of the study recommendations was that strengthening supervision and the development/implementation of management information systems need to be emphasized.

The HERA study was, however, limited to medicine supply management at hospitals and did not assess it at primary health care facility level. It must also be pointed out that the assessment was carried out on all pharmaceutical supplies in general, without examining the procurement and distribution of antiretrovirals (ARVs) specifically, in which case specialized principles of medicine supply management would have to be applied (quantification, storage, distribution, use, etc.).

In 2005, the MoHSW commissioned an assessment of the status of laboratory capacity to support the scale-up of ART. This assessment was undertaken within all hospital laboratories in Lesotho with assistance from the Clinton Foundation HIV/AIDS Initiative. This study had a limited scope, focusing mainly on the capacity of the laboratory services to conduct the following tests that are essential for care and treatment of people living with HIV/AIDS—

- HIV diagnosis
- CD4 cell count
- Clinical chemistry
- Hematology
- TB and common STI diagnosis

The study did, however, confirm that hospital laboratories experienced frequent and occasionally prolonged stock-outs of key reagents and consumables. Reliable supply of laboratory reagents and consumables was reported at only 7 of the 19 laboratories. Laboratory demands were often not met by the local hospital procurement systems, and inadequate supply and late delivery was common. This was reported to be primarily due to inadequate local hospital funds and late payment to suppliers.

The study’s findings noted that reagent and consumable costs are the largest component of laboratory testing and far outweigh the cost of instrument procurement. It went on to state that the overall clinical value and cost-effectiveness of the treatment program depends on the uninterrupted provision of reliable and cheap diagnostics. Furthermore, improved supply management would strengthen budget justifications at national level. Additional useful recommendations for the strengthening of supply management of laboratory consumables were also listed.
The study’s conclusion was that a primary objective of the laboratory system was to provide an essential diagnostic service in support of HIV care and treatment. The point is made that this assessment was the first full assessment of laboratory services in support of antiretroviral therapy in Lesotho and that its results should be used as baseline data for upgrading the capacity of laboratory services for HIV and ARV diagnostics. Specific areas requiring immediate attention were, for example, infant diagnostics, safety testing, supply chain management, quality management, and bio-safety. The study is scanty on the problems afflicting the logistics and supply chain, but provides useful data on which further detailed assessments can be based.

Confirmation of the extreme shortage of skilled health care workers, including doctors, nurses, laboratory technicians, and pharmacists throughout the health system, is found in a situation analysis of reproductive health commodities security. The shortage has resulted in staffing patterns that often leave health care delivery in the hands of overworked providers whose training and qualifications may not be sufficient for ensuring the quality of the services they provide. As a consequence, quality of care in most government health facilities is low.

The study reports that, “Another consequence of inadequate numbers of skilled staff is stock-outs, which are frequent for many types of commodities. There are supportive policies for reproductive health and family planning, generally sufficient commodities in the health logistics system, sufficient funds from either the GOL or development partners to finance commodities, and procurement systems are functioning. There are also reasonably effective logistics management information systems (LMIS), relatively efficient (albeit inadequate) storage facilities, and adequate transport for delivery of supplies from the central to the health service area (HSA) level and from most HSAs to health centers. The real deficiency is in the effective use, management, and monitoring of these systems. Data collected in the LMIS is not always reliable due to poor record keeping and late reporting. The data are not used effectively for forecasting (especially for contraceptives), monitoring and supervision, or for decision making about procurement re-supply, or inventory control. Staff are not sufficiently trained and motivated at every level to use the LMIS in order to prevent stock-outs.”

These observations, although directed at reproductive health commodities, could just as easily have been made in respect of laboratory reagents and other ART-related commodities.

Proceedings of workshops and reports of other collaborative forums held between the MoHSW and development partners also provided useful insight into the levels of the collective efforts that exist in the fight against the AIDS epidemic.
ASSESSMENT METHODOLOGY

Sampling of Facilities

The entire assessment team was involved in selecting, through sampling, facilities to be visited and the choice of stakeholders to be interviewed. In the case of the health facilities, the main criteria for including a site was that it had to be one of the national ART sites and that it provided laboratory services (this mainly is the case for most hospitals). Care was also taken to ensure that a representative number of CHAL facilities would be visited, and that all levels of facility (i.e., referral hospital, district hospital, filter clinic, or health center) would be included in the selected sites.

At the time of the assessment there were 121 ART sites registered with the MoHSW, comprising 1 regional hospital, 18 district hospitals, 4 filter clinics, 63 health centers, and 35 private sector sites.

The team selected 15 ART sites that included 10 hospitals (4 of which were CHAL hospitals), 1 filter clinic, and 4 health centers. The private sector sites were not included in this study (Annex F).

The assessment team, comprising consultants in the areas of pharmaceutical and laboratory services from SCMS and RPM Plus and officials in these areas from the MoHSW, was split into three data collection teams. Both disciplines—pharmacy and laboratory services—were represented in each team. Each team had a leader, whose major responsibility was to coordinate team activities (Annex G).

One CHAL hospital and one health center that were originally selected were not assessed. The team could not reach the hospital because of heavy rains. The health center was already closed at the time of the visit, the reason given being that the center normally closes early on a Friday afternoon.

Stakeholder Interviews

The Lesotho HIV/AIDS commodities supply chain system has several stakeholders that make different contributions towards the various components of supply chain management. During the stakeholder meetings, the team was provided with an overview of the current supply chain system (including quantification processes, procurement systems and processes, and inventory and distribution management at central, hospital, and health center levels) for HIV and AIDS-related commodities. The overview covered the specific stakeholder contribution to the total supply chain management system, their coordination with other stakeholders, and recommendations for future supply chain management system in Lesotho.

The interviews with stakeholders were guided by structured, open-ended questionnaires (Annexes A–C).
Data Collection Methods

The assessment team reviewed and adapted questionnaires developed by RPM Plus for assessing the pharmaceutical supply chain. The emphasis was on capturing details of the management of commodities through the supply chain, including the existence and use of standard operating procedures. Aspects of the pharmacy infrastructure, particularly those regarding storage conditions and equipment availability, were also included.

Another questionnaire developed by John Snow, Inc. was also reviewed and adapted for the assessment of the laboratory supply chain. Similarly, the sections of the laboratory facilities tool that involved the collection of details that had more to do with a description of the facility, rather than management of the supply chain of laboratory commodities, were excluded.

Two separate sets of questionnaires were used (Annexes D and E); the more detailed one for the hospitals in each case (i.e., pharmacy and laboratories) and the shortened version for the PHC facilities.
The pharmaceutical facilities and laboratory facilities questionnaires were tested at Queen Elizabeth II Hospital in Maseru. With regard to the pharmacy tool, the team agreed not to assess the area of “service provision,” as this had already been captured and described in detail in the recent HERA survey.

The questionnaires were completed during structured and open-ended interviews with a staff member on duty, followed by a quick inspection of the premises and data collection from records available. Depending on the level of management of the available staff members held, some sections of the questionnaires could not be completed in full.

Data Capturing and Analysis

Data for pharmaceutical and laboratory indicators was captured by the team members onto Excel spread sheets. The indicators were linked to major questions from the relevant questionnaires. Both qualitative and quantitative data was captured from the completed data collection sheets.

<table>
<thead>
<tr>
<th>Supply Chain Area</th>
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<th>Health Center Pharmacy</th>
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<tr>
<td>Availability of ARVs</td>
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<tr>
<td>Infrastructure</td>
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Table 2. Laboratory Services Indicators

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<th>Health Center Laboratory</th>
</tr>
</thead>
<tbody>
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<td>Quality assurance tests</td>
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<td>Supervision</td>
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<td>√</td>
</tr>
<tr>
<td>Laboratory testing services</td>
<td>√</td>
<td></td>
</tr>
<tr>
<td>Equipment availability and maintenance</td>
<td>√</td>
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</tr>
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OBSERVATIONS, FINDINGS, AND RECOMMENDATIONS

Pharmaceutical Services

Policy and Legal Framework

The key players in the pharmaceutical sector in Lesotho are the Pharmaceutical Directorate, NDSO, and their “clients,” the health facilities. The Directorate is responsible for the development of policies and the legislative framework and oversees implementation of policy and legislation. The NDSO is the pharmaceutical procurement agency for the public sector and, to a large extent, the private sector. Health care facilities are involved mainly in the supply of medicine to the end user.

The MoHSW Strategic Plan 2004/05–2010/11 states, “The Pharmaceutical management system in Lesotho is undergoing considerable transformation with the aim of making it more efficient, effective and equitable. A series of reviews undertaken in the last decade made significant recommendations for strengthening the pharmaceutical sector. These focused on policy development, legislation and regulation as well as institutional development. Recommendations made included, inter alia, the establishment of a Drug Regulatory Authority, National Drug Policy Committee, Pharmacy Board, as well as an Essential Medicines List, Standard Treatment Guidelines and National Formulary. To date, progress has been made on some of these undertakings. More is yet to be done.”

Findings and Discussion

WHO provided support to development the National Medicines Policy (NMP), which was finalized in 2005. The NMP highlights structures (e.g., the medicines regulatory authority, NDSO) to be developed, and objectives to be achieved in ensuring pharmaceutical service delivery.

The Pharmaceutical Directorate has developed a strategic framework in line with that of the Ministry of Health, to address the challenges and achieve the objectives highlighted in the NMP. However, little has been achieved as although the NMP was approved, it has never been distributed among the stakeholders.

The current pharmaceutical legislative tools are obsolete. The Dangerous Medicines Act of 1973 controls handling and movement of narcotics and psychotropics. The Lesotho Medical, Dental, and Pharmacy Order of 1970 regulates the practice of medical doctors, dentists, and pharmacists, and provides for the establishment of the Lesotho Medical, Dental, and Pharmacy Council.

The Dangerous Medicines Act is being repealed to give rise to the Drugs of Abuse Act and the Medicines Control Act. These two pieces of legislation are in draft form. The Drugs of Abuse Bill provides for the establishment of the Narcotics Bureau, a multisectoral committee whose main mandate will be to assist the government’s line ministries in developing policy on illicit drug movement. The Medicines Control Bill, once enacted, will establish the Medicines Control
Authority of Lesotho, which will be mandated to ensure the quality of pharmaceuticals entering and available in Lesotho through registration and licensing of pharmaceutical commodities and premises. Although it had been planned to have this bill tabled in Parliament before the end of 2007, this did not happen.

Internationally, it is the norm for a country’s medicine policy to be canvassed and discussed with all the stakeholders prior to being adopted as national policy. This way, its implementation, particularly when given expression through legislation such as the Medicines Bill, does not encounter any significant resistance. Consensus meetings were held with stakeholders to deliberate on the NMP before approval. The draft Medicines Bill has been submitted to the Ministry of Parliamentary Affairs for drafting and preparation for tabling before Parliament.

At the same time, there is a sense of urgency in getting the bill approved by Parliament so that the medicines regulatory authority can be established and available to assure the public that all medicines on the market in the country are safe, effective, and meet approved standards and specifications.

**Recommendations**

- It is recommended that finalization of the Medicines Bill be fast-tracked.
- It is also recommended that legislation be prepared for the establishment of a body to control the pharmacy profession.

**Organization of the Pharmaceutical Sector**

The Pharmaceutical Directorate (PD) represents the sector at the national level. The PD reports to the Director General of Health Services who, in turn, reports to the Principal Secretary of MoHSW.

The PD collaborates closely with the line programs, including, among others, the HIV and AIDS Directorate, the Disease Control Program, and the Family Health Division in the supply and management of pharmaceuticals, and, more specifically, HIV/AIDS commodities. It has a pivotal role in the supply chain of HIV/AIDS commodities, including ARVs and products for OIs in Lesotho.

The NDSO plays a major role in the supply chain management of pharmaceuticals. NDSO has the sole mandate to source and supply good quality and cost-effective medicines to public sector health facilities. NDSO has been established in terms of the legislation as a trading account of the Ministry of Finance, which provides technical expertise in the procurement, storage, and distribution of medicines to the MoHSW. It is accountable to a board, known as the National Drug Supply Committee (NDSC) whose members are mainly from the Health and Finance Ministries and development partners.
There are three main levels of health care in Lesotho. The referral hospital, Queen Elizabeth II Hospital, is considered a tertiary level facility. The district hospitals are the secondary level, and the clinics constitute the primary level of health care.

General medicines and ARVs are available on the EML. The list of general medicines available at the lowest health care level is, however, limited, and increases according to the services provided at the level of care.

CHAL facilities contribute to the provision of health care services in the remote areas of the country. CHAL hospitals also operate according to the government health care structure. ARVs are distributed at all levels of health care in the CHAL facilities. CHAL district hospitals distribute general medicines at a higher cost than the government facilities. There is also an option for patients to use the private sector. This practice is less common among the lower income group of the population. ARVs are available at minimal to no cost in all health facilities in both the private and the public sectors.

The private sector facilities, which are supporting the HIV/AIDS treatment program by seeing patients on behalf of the public sector, receive their ARVs from the HAHPCO once they meet the required criteria. HAHPCO is a unit that was established in the Pharmaceuticals Directorate to procure, store, and distribute ARVs. This was an initiative supported by external partners for ARVs to be handled outside NDSO, as there was a realization that NDSO did not have the capacity to manage the increasing ARV load.

After operating for some years, the mandate of HAHPCO was changed to focus only on assisting the hospitals to quantify their ARV requirements. The supplies, which were stored at the HAHPCO offices, were transferred to NDSO, which is therefore currently involved in the procurement, storage, and distribution of ARVs. However, HAHPCO still keeps an emergency stock of ARVs for distribution to the private facilities and to the hospitals.

Findings and Discussion

Over the years, the PD has been operating with only one or two persons, representing the pharmaceutical sector at national level. Currently, the PD operates with five pharmacy personnel—two pharmacists and three pharmacy technicians.

It is perhaps not surprising that very little attention has been paid to implementation of the Medicines Policy, as the same officials are engaged, on a full-time basis, in procurement activities through HAHPCO. It is also this shortage of staff that constrains the PD’s ability to provide comprehensive and meaningful support and supervision to medicine supply chain activities on the ground.

Recommendations

It is recommended that a forum be established to oversee implementation of the National Medicines Policy. Members of this forum would be managers from the PD and NDSO, and representatives of the various hospitals. The forum would include a representative of the Office
of the Director-General who would convene the forum, and development partners providing technical assistance to pharmaceutical services would also be invited to participate. The forum would meet every two months or quarterly. Its purpose would be to—

- Provide assistance to the PD by monitoring and evaluating its work plans and ensuring the implementation of recommendations from surveys and studies conducted in the pharmaceutical sector
- Provide coordination in the efforts and activities of partners providing technical assistance and donations
- Keep the Director-General informed and ensure that this office supports to efforts to improve pharmaceutical service delivery, especially with regard to the procurement, distribution, and rational use of ARVs and laboratory commodities

**Human Resources**

In the public sector, pharmaceutical service delivery at the different levels of health care is the responsibility of the pharmaceutical and nursing cadres. At the district hospital level, services are provided by both pharmacists and pharmacy technicians. The nursing cadre provides pharmaceutical services at the lowest levels of health care.

**Findings and Discussion**

In Lesotho, there are two higher learning institutions that contribute greatly towards developing pharmaceutical skills for both the public and private sectors—the National University of Lesotho (NUL) and the National Health Training College (NHTC) where pharmacists and pharmacy technicians are trained. The severe shortage of staff has persisted, however, as there are currently no posts available to absorb the output of the training institutions.

There is a severe shortage of staff at all health care levels and the problem has been aggravated by the increasing introduction of new programs within the health care system. A classic example is the establishment of ART centers in all health care facilities, where the services provided have clearly increased but without any change in the number of pharmaceutical staff employed. This situation has led to the existing pharmacy personnel being overstretched to meet the demands of the centers. GOL and CHAL hospitals have, on average, two pharmacy technicians per facility for the management of general medicines and ARVs.

The DHMTs were established under the Ministry of Local Government in an attempt to decentralize health care services. These structures were implemented without the recruitment of new staff. This change led to the most senior pharmacy personnel being moved to the DHMTs, leading to an increased workload for the remaining pharmacy personnel.

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iv The technical human resources in all the disciplines used in ART centers in the facilities are from the main hospital, causing a human resources shortage.
Observations, Findings, and Recommendations

The PD currently has the responsibility of facilitating recruitment of pharmacy personnel for all facilities. The Directorate rotates pharmacy staff among the health facilities in the public sector to improve pharmaceutical service delivery. More than 90 percent of the pharmacy personnel at all levels of health care have received training in medicines supply management.

MoHSW has embarked on a structural review for all health programs, including the pharmaceutical sector, under the Health Sector Reform Program. The revised organogram for the Pharmaceutical Directorate is an initiative which attempts to provide a number of critical positions. The organogram also enables the development of legislative structures to be operational to achieve the objectives highlighted in the Medicines Policy and the MoHSW Strategic Plan for 2004/5-2010/11.

![Figure 2. Organogram of pharmaceutical directorate](image)

A ten-year Human Resource Development Plan has been developed by the PD to ensure capacity building mechanisms within the sector to focus on the existing challenges of staffing. The plan was developed to address the dire need for pharmacy personnel and also to enable the smooth functioning of the proposed operational structure. There was, however, no indication that it had been approved for implementation.

The CHAL health facilities are gradually making use of pharmacy technicians and pharmacists to replace nurses in providing pharmaceutical services. This development has improved pharmaceutical service delivery at CHAL facilities. Pharmacy personnel at these facilities have also received extensive training in medicines supply management, but they still face enormous challenges. The failure of hospitals to provide pharmacy personnel with full control over operations of the pharmacy department, and lack of professional development are seen as factors leading to a high attrition rate of pharmacy professionals from these facilities.
The creation and filling of positions as indicated in the organogram would go a long way towards improvement of medicine supply management at all levels. This would begin to impact on the ability of facilities to produce accurate estimates of their medicine requirements and receive periodic supervisory visits.

Capacity should be created within the national health system to absorb most, if not all, of those graduates produced by the two training institutions at great cost to the nation.

**Recommendations**

The MoHSW needs to look at the creation of district and hospital pharmacist posts as a matter of urgency. The national human resource plan for pharmacy and the training strategy of the school of pharmacy at the National University of Lesotho need to be aligned.

**Medicines Supply Management**

In the public sector, general medicines and ARVs are supplied from a sole supplier, NDSO, to the health facilities. The health facilities are requested to seek source approval from NDSO before requesting commodities outside the NDSO network.

**Findings and Discussion**

The MoHSW realized that hospitals, both CHAL and government, were making use of different medicine supply management systems in the provision of pharmaceutical services. The most notable example was the use of different requisitioning, inventory, management, and distribution tools. The Ministry engaged the services of HERA to assess the existing situation, and thereafter assist the pharmaceutical sector in establishing standardized medicine supply management systems at both CHAL and government facilities. The deliverables for the external support were making available medicine supply management manuals spelling out the systems to be used, creation of the Lesotho SOPs, and the training of personnel in the implementation of such systems.

The assessment found, however, that only 17 percent of the hospital pharmacies visited had SOPs for pharmacy. This situation is undoubtedly due to the lack of support from the national level, more specifically in providing the necessary tools and ensuring their proper use. Clearly, there is still a lot of room for improvement as far as the use of the manuals and SOPs is concerned.

CHAL facilities procure their general medicines mainly from NDSO, but may also procure from any other suppliers of their choice. ARVs are supplied to CHAL facilities by NDSO at zero value as an attempt by government to improve access to essential health commodities. Emergency ARV supplies are distributed by HAHPICO to the CHAL facilities.
Recommendations

The medicines supply management manuals and standard operating procedures and forms developed by HERA should be printed and distributed widely for use. Efforts should be made to ensure that the tools are appropriately used to improve medicine supply management.

Financing of Medicines

Findings and Discussion

There are a number of vertical programs that are involved at different levels of the medicines supply chain, from developing and controlling the budget for pharmaceuticals to procurement, storage, and/or distribution within the MoHSW national HIV/AIDS program. The programs operate in parallel to the regular medicines supply management system for general medicines. For example, the budget for ARVs is developed and controlled by the HIV/AIDS Directorate, although the actual procurement is overseen by HAHPCO. The hospitals send their consumption data to HAHPCO for quantification of their requirements, whereupon HAHPCO generates a distribution list which is submitted to NDSO. NDSO has the responsibility of procuring, storing, and distributing ARVs to the facilities. The Disease Control Unit is involved in the quantification of TB medicines, while the Family Health Division stores are involved in the distribution of HIV/AIDS test kits and condoms. The HIV/AIDS Directorate also keeps and distributes STI medicines. Figure 3 below illustrates the complexity of the flow of funds and supplies. The various sources of funding for ARVs and other supplies are depicted under “Budgets” in the diagram.

A push system of distribution is used in the vertical medicine supply chain for the specific commodities, which are mostly HIV/AIDS related. On the other hand, a pull system of distribution is used for general medicines.
Financing for general medicines is done through the recurrent budget. Financing for ARVs is obtained from the recurrent budget as well as funding from development partners, more specifically Global Funding mechanisms. The recurrent budget for ARVs consumed by the public and private health facilities is prepared and controlled by the HIV/AIDS Directorate. The budgeting process for ARVs is highly centralized, and district health facilities do not participate.
in the process. Development partners provide funding for the procurement of HIV/AIDS medicines and other related commodities upon request by the government. There is, however, a lack of coordination of funding from development partners towards procurement of HIV/AIDS commodities.

Patients enrolled in the public and private health facilities do not pay for ARVs which are supplied through the MoHSW in order to ensure access.

**Recommendations**

There is a clear lack of coordination among the units in the MoHSW handling donated funds for the purchase of ARVs. At the same time, various developmental partners channel their donations of ARVs to different programmes and units in the MoHSW. Although their target is all eventually one and the same—the people using the facilities—their supply is subject to different sets of SOPs and reporting and monitoring systems. It is proposed that the Ministry consider the following measures—

- A uniform set of guidelines must be applied for all donations (medicines and funds) to the Ministry, with the possibility of a uniform fund, located in the Ministry, being established and through which all donations would be channeled.

- Storage of all medicines, including donations, must be the responsibility of NDSO, and all medical supplies, including donations, must be procured through NDSO.

- There is no doubt of the need for the HIV/AIDS Directorate to play a central role in all efforts aimed at battling the epidemic, including treatment. It is, therefore, vital that they work closely with the PD and NDSO in budgeting, procurement, storage, and distribution of ARVs and related commodities.

**Selection**

**Findings and Discussion**

The selection process is intended to be the responsibility of the National Pharmacy and Therapeutics Committee (NPTC) (which is not yet in place), in collaboration with the Hospital Pharmacy and Therapeutics Committees (HPTCs). A steering committee was formed to help facilitate the process, which included drafting the policy and developing the workplan for the establishment of the NPTC. Most of the hospitals have only just begun the process of establishing the institutional committees following training workshops facilitated by RPM Plus. At the time of the assessment, 46 percent of the hospitals had established pharmacy and therapeutics committees, but the majority was not yet functional.

Ad hoc review committees had been formed to review and develop the SOPs and the essential medicines list.
**Recommendation**

Establishment of the NPTC should be pursued as a matter of urgency and the health facilities supported in establishing the HPTCs.

**Quantification**

Quantification of essential medicines, including ARVs, has been one of the biggest challenges in the effort by the MoHSW to provide ARVs and related commodities.

**Findings and Discussion**

Ongoing assistance is being provided by counterparts, i.e., Clinton Foundation and MSH/RPM Plus, in developing a quantification tool to be implemented at facility level; in addition, staff will be trained in the tool’s use and its implementation will be supported.

ARVs are quantified by HAHP CO at the central level for all health care facilities receiving ARVs. There are challenges in the system, which are mainly due to the lack of supervisory site visits by HAHP CO, leading to facilities over-stocking or under-stocking on certain items. ARVs have been seen to expire on the shelves in some facilities where inventory is poorly managed.

There is generally poor reporting by health facilities, leading to incorrect quantities being distributed. HAHP CO has developed a supervisory schedule, which is not operational because of lack of staff as the personnel operating at HAHP CO are also engaged in other Directorate activities.

Collaborating partners such as the Clinton Foundation have provided support in training facility staff in inventory management of ARVs and reporting mechanisms. They have further provided a system of mentorship whereby an identified pharmacist within the MoHSW has been tasked to visit the facilities which are seen to be struggling with providing appropriate reports. The mentors are, however, not providing the PD and HAHP CO with reports after field visits, which would allow follow-up and further assistance.

A consumption-based quantification method was developed for essential medicines, while a morbidity-based method of quantification is used for ARVs. The quantities for other medicines used for opportunistic infections, e.g., TB are determined by the Disease Control Programme which uses a different consumption-based quantification method for that purpose.

The lack of standardized quantification methods and tools used by the different authorities has compromised the ability of the facilities to provide reliable consumption data for use by NDSO for procurement.

**Recommendation**

Streamline the process of quantification for all essential medicines. A uniform quantification tool and standard procedures, driven by the PD with the close collaboration of NDSO, the HIV/AIDS
Observations, Findings, and Recommendations

Directorate, and the TB unit, need to be developed and applied uniformly by all public health facilities as well as CHAL health facilities.

**Procurement**

As mentioned before, NDSO is the main procurement agency for pharmaceuticals for government facilities. The procurement agency has been established as a trading account and is fully owned by the government. NDSO reports to the NDSC, on which the Ministries of Health and Finance, CHAL, WHO, and the United Nations Children’s Fund are represented.

According to Government Gazette No. 19 of March 2, 2007: “The purpose of the Trading Account is to promote the health of the people of Lesotho by developing, implementing and maintaining an equitable and reliable system for procurement, storage and distribution of medicines and medical supplies of acceptable quality to all Health Institutions in Lesotho at the lowest possible cost.”

**Findings and Discussion**

HERA has provided support in the review and development of the procurement manual and SOPs at NDSO, which has the capacity to procure by international competitive bidding and uses this method to purchase ARVs and commodities. NDSO’s capacity has been heavily supported by a consultant providing technical assistance in procurement and there is concern because that consultant’s contract is expiring soon.

Requirements for procurement are determined from past consumption data, as hospitals are not providing forecasts. But capacity is being built at facilities to enable quantification data to be forthcoming. It is envisaged that in the Financial Year 2009/10 the facilities will be able to provide their needs to NDSO to facilitate procurement of pharmaceuticals. However, this may not be achievable without staff numbers at the facilities being increased as indicated previously.

In terms of donated commodities, it was found that 80 percent of the donations received at the facilities had been procured from NDSO. The rest were sent directly to the facilities by some of the donor agencies or units within the MoHSW, most commonly on an ad hoc basis in response to sporadic shortages. Of all the donated commodities found at the facilities, 60 percent were on the country’s EML—a low percentage. In at least one facility, it was found that only 89 percent of the labels on the medicines were in English (this latter case was highly exceptional and has to have been an isolated case). The existence of and adherence to some policy on medicines donations would ensure that all donations were channelled through the central medical store, NDSO. This approach would ensure that certain basic principles are observed, such as the requirement for all medicines distributed to and used in the public sector to be on the EML (this policy might not be in force in Lesotho currently, but is prevalent in many developing and developed countries and is encouraged by WHO).

The healthcare system relies on NDSO for quality assurance, as there is no drug regulatory body established legally to inspect manufacturers and register medicines. As the November 2006 HERA report states, “NDSO did develop a quality assurance policy document, but does not have
the capacity to implement all aspects of the comprehensive document. Medicines supplied by new suppliers are sent to South Africa for quality testing.”

**Recommendation**

Due to the increasing volume of donations, coupled with the decision taken for NDSO to procure and distribute laboratory commodities, NDSO should co-opt a laboratory specialist to be a member of the tender panel when procuring laboratory commodities.

**Storage and Distribution**

**Findings and Discussion**

Storage space at NDSO is inadequate. There is an enclosed area within the store dedicated to ARVs, but due to the space limitations, there is spillover of the ARVs to the rest of the stock items. NDSO received financial assistance from the World Bank for an extension of the warehouse. This extension has been completed and is in use. The warehouse is equipped with pallets, trolleys, and stock cards. Narcotics and flammables are adequately stored and secured. The shelves for the new warehouse have not been installed. Stock items, which are supposed to be quarantined, are still placed on pallets and not enclosed. The stock thus needs to be reorganized to maximize the use of available space.

RPM Plus provided assistance to NDSO with the implementation of a new computerized warehouse management information system, ORION@MSH, which was intended to replace their existing Pegasus software. This system was developed for MSH by a third-party company 3i with funds from the Bill & Melinda Gates foundation. Staff was trained on the different modules of the system, the master tables were created, and computerization of all NDSO operations started. There were indications that some of the components of the software were not fully functional and its overall application was still erratic.

Limited storage space is a problem that affects all the facilities. General medicines and ARVs are stored in the main pharmacy store except for Queen Elizabeth II, Maluti, and Motebang Hospitals, where ARVs are kept at the ART centre. In terms of convenience, most pharmacies visited (92 percent) were found to be suitably located on the hospital grounds, meaning that they were not isolated from related units, and were easily accessible to patients (figure 4). Of most serious concern was the low number of facilities where the temperature in the pharmacy was properly controlled. Lack of temperature control poses a serious threat to the stability of some medicines. The stores are equipped with shelves and, in some facilities, pallets. Seventy-five percent of facilities still store supplies on the floor, and that percentage is still unacceptably high.

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v Before finalization of this report, the ARVs and OIs were placed in a designated area in the new warehouse.

vi Implementation of ORION@MSH at NDSO was halted in early 2008. In October 2007, an evaluation of ORION@MSH implementation showed some glitches that needed to be fixed. The contractor (“3i”) was contacted only to find out that the contract with MSH at the global level had come to an end. Following months of unsuccessful negotiations between the top management of MSH in the United States and “3i” to secure a maintenance and support contract as originally planned. It was finally decided in February 2008 that it would be in the best interests of NDSO to stop the implementation of ORION@MSH. RPM Plus/SPS was to assist NDSO with the implementation of an alternative system. To this end, an independent consultant was hired to identify NDSO priority requirements and identify the best solution for NDSO.
Observations, Findings, and Recommendations

(figure 5). The number of facilities where expired items were observed is also a concern. Notwithstanding the above observations, it can be concluded from the figures that the staff of the facilities are committed to maintaining a clean and safe environment.

![Figure 4. Pharmacy general aspects and storage](chart1.png)

![Figure 5. Storage conditions of bulk stores](chart2.png)

Figure 6 is a graphic depiction of the security situation in the hospital pharmacies and the suitability and adequacy of the premises for the conducting of good pharmacy practice. Only 36 percent of pharmacies were found to have fire extinguishers, the floor space was inadequate in
50 percent of facilities for the activities and storage in the pharmacy, and in 75 percent of cases, the facility layout was not adequate for the efficient and smooth flow of processes and activities. Access to the area where medicines are kept in the pharmacy is normally restricted to those authorised to handle medicines, for safety and security reasons. Delivery area refers to the area where supplies are delivered to the pharmacy—this relates to the safety and security of the medicines against the elements and possible pilferage. In 67 percent of facilities, the delivery area was not covered. The last group of indicators aimed to establish the types of security systems in place.

Bulk stores refer to the room where supplies are delivered originally from the suppliers and from where the required amounts are transferred to the dispensary on a daily basis. Here, too, issues of adequacy of space and security are just as important. Ventilation and the condition of the ceiling are important factors in ensuring that medicines susceptible to deterioration in quality in high temperatures are well protected. As can be seen from figure 7 below, most of the pharmacies were found wanting in respect to these vital infrastructural requirements of security and adequate storage size. It was found that access to the stores where general medicines and ARVs are kept is not limited to authorised persons at the health facilities. There was, however, adequate ventilation in most facilities.

**Figure 6. Pharmacy access and security**
In the area of cold chain maintenance, all hospital pharmacies visited had refrigerators, and in almost all of them (92 percent,) heat-sensitive items were kept in the refrigerator (figure 8). What was wanting was adherence to the SOPs for cold chain maintenance. In more than half of the pharmacies, there was no thermometer in the fridge, and in only a quarter of the cases was the temperature checked and charted twice daily as required by cold chain procedures.
Electronic and manual systems are used to control inventory at NDSO, while in the health facilities the inventory control systems are solely manual at the lower health care levels and a mixture of both manual and electronic at the district health care level. Just half of the hospital pharmacies had computers, and only a quarter had printers (figure 9).

![Figure 9. Pharmacy computer equipment and back-up procedure](image)

The availability of computers was not, however, an indication of a computerised stock management system. As is evident from figure 10 below, a computerised stock control system was found in only 25 percent of the hospital pharmacies.

![Figure 10. Stock management systems](image)
The manual inventory control system makes use of stock cards. Health facilities are in the process of introducing redesigned stock cards while most hospital have the cards and are using inventory threshold levels to manage their inventory. An important aid in inventory management is regular stock-taking. The assessment team found, however, that only 67 percent of the hospital pharmacies had performed a stock take at least once during the last year.

There is vast progress in inventory management of general medicines, but not much improvement in the inventory management of ARVs, in instances where the bulk stock is stored at the ART centers. A pull system is used to distribute general medicines to health facilities, and a push system is used to distribute ARVs and TB drugs to the health facilities. It is, however, envisaged that the push system for distributing ARVs and TB drugs will change to a pull system once capacity to quantify needs has been improved at facility level.

**Recommendations**

- There is an urgent need for storage space to be expanded at NDSO, again, due to the increased volumes of supplies being received. Even if additional funds from the national office were not forthcoming, consideration should be given to NDSO reviewing its inventory management and distribution levy, which could be used for the necessary capital expenditure projects. Improvements should include building expansion, purchasing up-to-date equipment, and additional skills capacity building.

- Due consideration needs to be given to ensuring that a permanent solution for a computerized management information system for NDSO is found and implemented.

**Medicines Availability**

**Findings and Discussion**

HERA reported that in 2006, a fleet of 6 NDSO vehicles distributed medicines to approximately 500 clients with a 75 to 90 percent service level. NDSO’s capacity to maintain such relatively high levels of service delivery is, however, gradually being eroded by the increasing volume of donations, particularly ARVs. There is no added funding for the increased inventory and distribution costs. The management of NDSO was considering ways of implementing a service levy that would compensate for the additional load in an equitable manner.

Indeed, the assessment team was able to confirm the high service levels described by the HERA report. Most of the facilities were found to have over 80 percent of the basic ARVs in stock, with variations in the availability of certain products from facility to facility. If anything, there was more over-stocking of certain products than shortages. The assessment team was able to confirm the shortage of double-strength co-trimoxazole (donated by the Clinton Foundation for the TB program) in most of the facilities. There were, however, large stocks of single-strength co-trimoxazole available in most of the facilities. The availability of the alternate product seemed to go unnoticed, as people seemed to concentrate on what was reflected on the double-strength product’s bin card, which was zero in many cases.
It was also clear that there was a serious need for a redistribution procedure, and for a supervisor who would be in a position to communicate overstocking and shortages to all facilities to facilitate redistribution of excess stock. It was not surprising that all of the facilities visited by the assessment team reported that they had had medicines expire on the shelves at one time or the other in the past year.

The hospitals are responsible for distributing general medicines and ARVs to the clinics. Once the DHMTs are fully functional, it is envisioned that clinics will be ordering for themselves and NDSO will distribute the medicines to one central point for further distribution to final destinations. Medicines are distributed to user departments from the main pharmacy store.

Although the assessment team had been informed that a decision had been made within the MoHSW to have the procurement and distribution of all laboratory commodities assigned to NDSO, it became apparent that the NDSO management had not been advised of this decision. The decision would, however, seem to be sound, given that the major reason for the shortage of reagents and other laboratory commodities at facilities appeared to be the lack of logistics expertise in the supply chain. It is also clear that for NDSO to successfully take over this role, the appropriate skills in the area of laboratory services would have to be added.

**Recommendations**

- A solution needs to be found to the rising inventory and distribution costs at NDSO arising from the increased volumes of donated ARVs and other commodities. This could include support to NDSO’s study to look into the possible imposition of an administration fee on inventory and distribution services

- To address the problem of medicines expiring on the shelves, the redistribution policy needs to be disseminated among all the hospitals and PHC clinics and, if necessary, discussed in special workshops

- While it makes sense to have the procurement and distribution of laboratory commodities transferred to NDSO, it is recommended that this be preceded by the placement at NDSO of the necessary skills, followed by the development of a comprehensive procurement plan

**Medicines Use**

Rational medicines use depends on improvements in diagnosis, prescribing, dispensing, and appropriate use of medicines by patients. According to the National Medicines Policy, “Rational medicines use is an area with potential for improvement in Lesotho. Surveys have shown that 54% of prescriptions contain one or more antibiotics, and on average 2.95 items are prescribed per encounter. Prescribers hardly have any objective medicine information at their disposal, except for wall posters from pharmaceutical companies. Dispensing is haphazard: there are no proper labels, and not enough time to explain rational use to patients.”
Findings and Discussion

Although the STGs and EML have been developed and available for use for quite some time now, they were not distributed to health facilities. It is evident that the guidelines can no longer address the current disease patterns prevailing in the country, and need to be reviewed. It is agreed that establishing the NPTC and HPTCs to facilitate the review of these guidelines is long overdue.

The delay in the appointment of the NPTC has led to fragmented efforts toward developing and reviewing STGs. The different programs are developing their own guidelines to address the prevailing burden of disease. The HIV/AIDS unit is currently spearheading the review of HIV/AIDS STGs, and the program is now involved in sensitizing prescribers and dispensers to the existence of the STGs.

The TB program has also developed its own treatment guidelines, which are now in use.

Prescribing of HIV and AIDS medicines is the responsibility of medical practitioners in both GoL and CHAL facilities, with pharmacists and pharmacy technicians at hospital level carrying out the dispensing. Prescribing and dispensing is the responsibility of the nursing cadre at health center level. All personnel involved in both dispensing and prescribing at all levels of the healthcare system have been fully trained.

Private practitioners receive ARVs from government once they meet the required criteria under the Public-Private Partnership program. One criterion is for the private doctors to have, as a minimum, a trained pharmacy technician employed to dispense the ARVs and other general medicines. The public sector does have programs where pharmacy personnel and prescribers in the private sector receive continuous professional development in the area of HIV and AIDS.

Recommendation

It is recommended that the NPTC be appointed as a matter of urgency and that a timetable be prepared for the review, dissemination, and implementation of the STGs and EML.

Supervision

Findings and Discussion

Supervision of pharmaceutical services in the public sector is the responsibility of the PD. Limited supervision, or the lack thereof, has been one of the biggest challenges in the PD. At the ART centers there have been regular reports of ARVs expiring on the shelves. Furthermore, medicines are not available where they are required but found in large quantities where they are in lesser demand or not required at all. No provision is made for redistribution of stocks between facilities.

A supervision checklist was developed by HERA to assist in conducting the supervisory visits. The current staffing levels at PD, however, simply do not allow for the implementation of the
supervisory tool. It is accepted that very little can be done to solve the problem of supervision until the required numbers of pharmacist and pharmacy technician posts have been established and filled in the districts.
LABORATORY SERVICES

Laboratory services are one of the most critical components in the delivery of an effective quality health care system. Laboratory services provide the basis for good clinical diagnosis, patient management, and monitoring in addition to providing an objective means to manage patients’ response to treatment and monitor disease trends. The ART program is a complex process which requires close surveillance by health care providers, careful adherence to therapeutic regimes and access to laboratory facilities for continual testing and monitoring so that therapy regimes can be adjusted accordingly.6

Fully functioning laboratory services providing reliable, valid, and timely results are required to support the HIV/AIDS and TB package of care and treatment, including the diagnosis of HIV/AIDS and TB infection, monitoring of ART and identification of OIs at each level of care. Like ARVs, uninterrupted availability of laboratory commodities (functioning equipment, test kits, reagents, and consumables) is mandatory support to the ART program.7 Unlike pharmaceuticals, little attention has been given to the particular need for a laboratory commodity management system. In most cases, poor laboratory management has created many problems at facility level such as the shortage of reagents to conduct the most critical tests. It is thus proposed that the ART program should concentrate on those aspects of equipment and supply chain management at facility level that are required to realize a fully functional HIV/ART diagnostic and monitoring service.8

Organization, Policy, and Functional Framework

Reliable laboratory services can only be achieved when policies and standard operating procedures are developed and implemented. A national laboratory policy is a prerequisite for the development of coordinated strategies to address the problems of HIV/AIDS and TB. The national laboratory policy provides the necessary guidance in improving and maintaining laboratory services at an optimum standard. The policy provides the framework required in the development of national technical guidelines to support cost effective quality health care at all levels.

The Lesotho HIV/AIDS Strategic Plan 2006-2011 is silent on laboratory services in all aspects of scaling up the ART program except for a mention of HIV testing, counseling, and safe blood.

Findings and Discussion

The laboratory services in Lesotho are organized on three levels: the National Central Laboratory, District Hospital Laboratories, and Health Centers.
Lesotho has one central hospital laboratory whose role it is to perform routine diagnosis and develop policy and technical guidelines (quality assurance, safety, SOPs, etc.). This laboratory is also responsible for surveillance and research in the country.

There are 18 district hospital laboratories, 9 of which are Government-owned and 9 operated by CHAL. To support the ART program, the health centers’ or clinics’ role is to perform HIV testing. Other specimens are collected and transported to the nearest district hospital laboratory.

At the time of this assessment, the National Lesotho Laboratory Services (NLLS) had no laboratory policy or strategic plan in place. Of the hospital laboratories, 83 percent reported that the SOPs for performing tests had been developed, compiled in a manual, and distributed in August 2007. The SOPs were, however, distributed without any training on their use. In all seven hospital laboratories assessed, there were no written safety guidelines except for Scott Hospital Laboratory which is supported by Médicine Sans Frontières (MSF). They had some written guidelines on postexposure prophylaxis for HIV and hepatitis.

**Recommendations**

- In view of the above issues, it is of the utmost importance that a national laboratory policy and strategic plan be developed to provide guidance and a framework for improving and maintaining the quality of laboratory services at optimum standards.

- A national strategic laboratory plan, as agreed to by members of a Lesotho delegation to the landmark January Maputo meeting on harmonization and standardization, needs to be developed.
Laboratory Services

- National Technical SOPs relating to safety, quality assurance, equipment maintenance, logistics, and information management systems should be developed and distributed, and laboratory staff trained at each level as appropriate.

**Human Resources**

A fully functional laboratory service requires adequate numbers of laboratory staff at each level of care. WHO recommends that at least two members of staff at each health center laboratory, six at each district hospital laboratory and three in each section of the Central Laboratory be deployed. These numbers can, however, be revised according to the laboratory’s workload and the country’s laboratory policy.

Poorly trained laboratory staff can be costly to the ART program because they can contribute to errors in test results, shortened life of laboratory equipment caused by improper use, and wastage of reagents and supplies. Laboratory monitoring tests for HIV/AIDS patients on ART requires qualified laboratory staff.

**Findings and Discussion**

The NLLS has two management positions—the Director of Laboratory Services and the Laboratory Manager. They are both based at the Central Laboratory in Maseru.

All seven hospitals assessed have qualified laboratory technologists and technicians who hold degrees, diplomas, and certificates in biomedical sciences.

![Figure 12. Distribution of qualified staff](image)
Figure 12 above shows that Queen II Hospital Central Laboratory has 32 laboratory technologists, while the number of qualified laboratory staff in the district hospital laboratories varies from two to six persons.

Three-quarters of the district hospital laboratories visited have only two laboratory personnel. In the health centers, lay counselors perform HIV testing because there are no qualified laboratory staff. Thus all specimens for investigation are referred to the nearest district hospital in the area. Lesotho has one laboratory training institution with only two lecturers, so the output of qualified laboratory personnel is low. It was reported that the MoH is now in the process of implementing a human resource plan 2007-2010 that will address this.

All the laboratory personnel in the facilities assessed reported that since their employment, they had never attended any refresher course or workshop on laboratory commodity management.

All the laboratories assessed have qualified laboratory staff, although district hospitals appear to be understaffed. This finding may be due to poor distribution of laboratory personnel in relation to workload, poor incentives, poor salaries, and insufficient number of laboratory personnel in the country. Typically, the health centers refer all specimens to the district hospital laboratories. This leads to high turnaround time for results, causing patients to return on subsequent days for their results and increasing their transport costs.

Recommendations

- Staffing levels and distribution of qualified laboratory staff should be reviewed in accordance with the human resource plan, current workload, and test profiles performed at each level of care to support the ART program. Policies and procedures for re-deploying staff should be reviewed to address staff shortages at overloaded laboratories.

- After basic laboratory training, laboratory staff need to maintain competence in laboratory procedures, which can be achieved through continuing education in the form of on-site and competency-based training. This training should include logistics commodity management (including quantification and supply planning).

Financial

Financing of laboratory services includes activities ranging from planning and budgeting, generating financial resources, monitoring operating costs, and workload in the laboratory, and seeking and implementing measures to balance costs of running versus available funds to operate the laboratory.

Findings and Discussion

The GoL provides 70 percent of the funds for laboratory services (infrastructure, equipment, supplies, and reagents). The balance (30 percent) comes from cooperating partners. Laboratory Services have a separate budgetary line for supplies/reagents and a special expenditure budget
Laboratory Services

for equipment. The district laboratories develop their own plan and budget according to the ceiling allocated by the MoHSW.

Laboratories assessed seemed to have adequate funds to use for laboratory commodities but reportedly had no control over the funds generated from the laboratory tests. The assessment team was told that these funds are collected by the administration of each health facility and then allocated to the general health facility budget.

Recommendations

- A national strategic laboratories plan should be developed to address issues around the capacity of laboratory personnel in planning and budgeting.

- Further research into where the revenues generated from the laboratory tests are redistributed to is required. These funds could potentially be used to strengthen laboratory services as appropriate.

Logistics Management Information Systems (LMIS)

LMIS is the management of laboratory commodities (reagents, consumables, supplies, and equipment) in a systematic and standardized way, and includes the collection of data required to manage commodities. Tools used for recording data are stock cards, requisition forms, registers, and report templates/formats which should be generated periodically. The extensive number of commodities used by laboratories makes logistics management more complex.

All essential basic tests required at each level of care to support the ART program are performed at all hospital laboratories except for microbiology, which is only carried out at the central laboratory. The health centers perform only HIV testing and collect other specimens which are then transported to district hospitals.

During this assessment the indicators used to assess inventory management practices for laboratory commodities were the formula used to calculate orders, current stock levels, availability of basic reagents and supplies, occurrence of stock-outs and the presence of expired items.

Findings and Discussion

The assessment team found that 67 percent of the laboratories assessed did not have a set minimum stock level for reagents and consumables at which orders needed to be placed, while 83 percent reported that they did not have maximum stock levels for reagents and consumables.

Figure 13 shows how the laboratory staff determine how much to order. Thirty-three percent of laboratories used average monthly consumption, 17 percent used number of tests performed, 50 percent order when stock is low in the laboratory, and 17 percent did not know.
It appears that knowledge and skills in stock management is inadequate in all of the laboratories as there are no developed LMIS guidelines on calculations or SOPs on how to determine orders. In most cases, laboratory staff use their own judgment and best guesses.

![Figure 13. Data elements used to calculate quantity to order](image)

Eighty-three percent of the laboratories ordered reagents and supplies from private suppliers while 33 percent of laboratories responded that orders were sent to NDSO.

Of the hospital laboratories assessed, 50 percent reported that they placed orders monthly and 33 percent quarterly. In the last year, an order for hematology reagents took three months longer than anticipated. The reason given was that the supplier ran out of stock from manufacturers and funds were not released in time to purchase the reagents and consumables required.

Sixty-seven percent of laboratories said that they had no stock cards and thus did not conduct a physical inventory of reagents and supplies.

Less than 50 percent of the laboratories visited send reports to the Central Laboratory and District level on stock status, laboratory tests performed, and surveillance reports. Only 17 percent of the sites reported that the forms they complete are integrated with the Hospital Management Information System.

All laboratories reported that they had no written guidelines for storage of laboratory supplies according to their specifications. In most cases, the storage space had poor ventilation and was small, and there were no cupboards for flammable reagents. Thirty-three percent of all laboratories reported that reagents were not stored according to the first expiring, first out (FEFO) practice. None of the laboratories practised the separation of damaged/or expired supplies from usable products. Seventeen percent of the laboratories responded that cold chain items were not stored at appropriate temperatures due to refrigerators being too full and space not being available.
The distribution of laboratory commodities is partly integrated across all programs (HIV test kits, CD4 count reagents, TB reagents). The supplies are collected from the central laboratory store by the facility vehicle. Some hospitals reported that the problems experienced relating to transport were attributed to drivers coming back without supplies, giving unreasonable excuses such as the supplies not being urgent, or simply that they forgot. Management and supervision of this component of the supply chain is poor.

At the time of the assessment, it appeared that some of the laboratories had basic reagents and supplies to support the ART program. In 2007, however, hematology reagents were reported out of stock for a period of three months. It was, therefore, difficult to determine the stock status of the reagents and supply as stock records (stock cards) are not kept in the laboratories. Inventory management practices were poor at most of the laboratories assessed.

Almost no inventory management tools were available in the laboratory facilities. Fifty-three percent had stock cards to keep track of reagents. Only 33 percent of laboratories had and used order books or requisition/issue vouchers for ordering and receiving supplies. Seventeen percent of laboratories had stock status reporting forms. None of the laboratories visited had expiry/loss/damage report forms, stock exchange forms, and expiry of kits monitoring forms. Meanwhile, 83 percent had standard printed laboratory test requests and reporting forms.

There is a need to standardize inventory tools and procedures for recording and storing information. Among the laboratories assessed, there was a wide variation of forms used in the laboratory. The laboratory staff members at each level of care are involved in quantifying, ordering, and procuring laboratory commodities. Therefore, there is a need to build capacity for laboratory staff in LMIS.

**Recommendations**

- A national list of essential laboratory commodities for each level of care should be developed in accordance with the policies and standards of the basic HIV/AIDS package. The procurement should be aligned with this essential list.

- A national logistics system for laboratories commodities should be designed and implemented in order to ensure continuous availability of essential laboratory commodities, including standardized stock management procedures, ordering forms, record keeping forms.

- A national quantification exercise should be planned and training conducted to strengthen and build capacity for the laboratory personnel in forecasting, budgeting, and supply planning for laboratory commodities.

- As it had been decided that all the laboratory commodities should be procured, stored, and distributed by NDSO, it is advised that NDSO recruit and train a laboratory specialist to oversee the management of laboratory commodities.
Equipment and Infrastructure

A fully functional laboratory must have good working equipment and a maintenance plan in place. WHO recommends that a minimum standard laboratory should have electricity, running water and basic essential equipment to support ART programs.\textsuperscript{10} Guidelines on standard equipment are critical in laboratories. The lack of guidelines results in inappropriate equipment being purchased and donations thereof being accepted.

Findings and Discussion

Most of the laboratories assessed had basic essential equipment which was well maintained. The central laboratory, however, had no distiller. Fifty percent of laboratories had an equipment maintenance plan, and 67 percent of laboratories assessed had equipment maintenance and daily cleaning schedules for performance on the equipment (FACS count, safety cabinet, hematology analyzer, and chemistry analyzer). Thirty-three percent of laboratories had no equipment maintenance schedule. Fifty percent of laboratories maintain temperature records of the refrigerator/freezer, and fifty percent had adequate glassware for preparation of reagents.

The infrastructure of the central laboratory was in a bad state. There was poor ventilation in the chemistry and hematology laboratories, which have equipment requiring cool temperatures for their operation. Eighty-three percent of district laboratories assessed had a good, well maintained, and clean working laboratory area.

In 67 percent of the district laboratories, the external walls were in good condition, and laboratories were well ventilated and well lit. Fifty percent had sturdy shelves to store reagents and supplies, lockable cupboards, an indoor patient waiting area, and secure laboratories with no access to unauthorized personnel.

Only thirty-three percent of laboratories had windows with security bars, access to safe drinking water for staff, and working fire extinguishers. None of the laboratories assessed had staff rooms for tea breaks.

Most of the laboratories assessed lacked space and equipment to ensure proper storage of reagents and supplies. Seventeen percent of the assessed laboratories reported that there were no refrigerators to store supplies requiring a cold chain system. It is essential to provide and ensure that there is adequate, well-ventilated storage space and equipment, and that the laboratory commodities used to support the ART program are of good quality in order to provide reliable and accurate results.

All the laboratories had service contracts with the suppliers. In at least one laboratory, it was reported that when the equipment broke down an engineer would be called in from South Africa. Equipment management guidelines are critical in the laboratories. Lack of such guidelines results in inappropriate equipment being purchased, a poor procurement cycle (lack of spare parts), and equipment damaged from improper use by untrained staff. Lack of a maintenance plan leads to the inability of the laboratory to provide quality reliable services.
Recommendations

- A standard list of essential equipment with specifications for each level of care and services should be developed.

- Guidelines on an equipment maintenance plan should be developed and the budget for equipment maintenance included.

- Adequate space in the laboratory should be made available to include a staff room.

- If biosafety guidelines are nonexistent, they should be developed to ensure that safe good laboratory practices are adhered to.

Quality Assurance

The availability of excellent laboratory tests does not automatically guarantee reliable results. Adherence to SOPs is paramount to obtaining quality and reliable results. Each of the steps involved (that is, client identification, sample collection, testing, interpretation of results and recording) must be critically analyzed to ensure quality controlled products. Appropriate kit and reagent storage among others must be carried out to assure achievement of quality controlled products.

Quality assurance (QA) is the total process that guarantees that the final results reported by a laboratory are as accurate as possible. The components of QA are internal quality control (IQC), external quality assessment (EQA), and performance improvement.

A QA program is a dynamic and ongoing process of monitoring reliability and reproducibility of results that permits corrective action when established criteria are not met. Ideally, each laboratory performing testing procedures should establish and implement a QA program to monitor and evaluate laboratory functions and services throughout the total process, that is, through internal quality control, external quality assessment, and standardization. High-quality laboratory performance ensures that the laboratory results obtained are reliable, precise, and accurate.
Findings and Discussion

Figure 14 shows that 33 percent of the assessed laboratories had available written QA policies and procedures.

While all laboratories (100 percent) reportedly calibrate the equipment daily and use commercially available quality control materials, only 50 percent included known positive and negative controls to the new batch of reagents or stains. Thirty-three percent who responded did not know what to do.

Sixty seven percent of laboratories visited could not produce their QA guidelines. All the district laboratories visited reported that they are participating in the EQA program conducted by NHLS of South Africa.

Recommendations

• All laboratories should have written policies and procedures for all activities. These documents will assist in continually assessing the total testing process to identify areas that need improvement, provide a basis for troubleshooting, and to define mechanisms to prevent the reoccurrence of problems.

• It is recommended that a QA manual be made available in all laboratory facilities and that laboratory staff be trained on QA.
ROLE OF DEVELOPMENTAL PARTNERS IN THE LESOTHO SUPPLY CHAIN

Organization of Donor/Support Efforts

Lesotho’s HIV&AIDS program has development and collaborative partners that are involved in different activities related to the supply chain management of ARVs, OIs, and laboratory supplies. Not all partners were met during the assessment period, nor had it been the intention to meet all of them as it was somehow limited to the organizations that play a significant role in the area of HIV and AIDS. The selection of those was based on advice provided by MoHSW and USG officials. All these organizations have their main offices in Maseru.

The World Health Organization (WHO)

The WHO office has an HIV&AIDS Advisor in addition to the Country Representative. WHO has been providing assistance with laboratory strategic planning and policy development. Another mission is due to be in country during the last two weeks in January to continue this work.

WHO/Afro has a mission being negotiated for pharmaceutical supply management (PSM) technical assistance. A consultant has been identified and prepared to look into mainstreaming procurement, establishing a supply management system, and training staff on LMIS and test kits.

The International Center for AIDS Care and Treatment Programs

The International Center for AIDS Care and Treatment Programs (ICAP) is managed by Columbia University and has a Country Director as well as a Country Coordinator. Funded by PEPFAR, the funding level for Lesotho is approximately USD 1.3 million—the smallest ICAP country budget. The program started in October 2005 and is planned to continue until the end of PEPFAR (currently through September 2009). Ninety-five percent of its 16 staff members are technical personnel.

ICAP is currently working in nine areas with a plan to cover the four southern districts. ICAP works in partnership with the HIV/AIDS Directorate and Family Health Department, Prevention of mother-to-child transmission (PMTCT) at health centers and hospitals to provide ARVs and laboratory services.

ICAP uses indicators from PEPFAR, MoHSW, and Columbia University to measure the success of the organization in meeting its goals and in providing services. The major indicators used are testing rate of pregnant women, percentage of women put on prophylaxis, how many babies are tested, and how many babies are put on prophylaxis.
ICAP is involved in the following supply chain management activities—

1. Policy development by providing input on HIV testing policy; participation in a technical working group on HIV test kits, reviewing and advising on HIV/AIDS and PMTCT guidelines, and reviewing STGs for ART

2. Program management through participating in the PMTCT technical working group and the Family Health technical advisory committee

3. Human resource development (e.g., staff hiring, training, supervision) through empowering staff at the site level, providing on-the-job training and continuous supervision (they visit sites at least 3 times a week)

4. Procurement and/or distribution through supporting emergency, ad hoc procurement of CD4 reagents and small equipment such as thermometers and scales

5. Clinical services through providing clinical mentoring, a 24-hour hotline, and provision of direct treatment services for very special cases

6. Technical assistance to other organizations in the country; although not formally, they provide support for training and collaborate with other implementing partners such as the Clinton Foundation on infant diagnosis and Baylor University on pediatrics

7. Multi-disciplinary team meetings held monthly at the sites, and six monthly review meetings are held.

The GFATM

The GFATM has a fund coordinator who heads the GFATM Coordinating Unit. The MoHSW started implementing GFATM-funded activities in 2004.

It has nine staff members: five technical (two for M&E, two to provide technical assistance which are supported by the World Bank and the Global Fund, and a coordinator) as well as four who provide administrative support. The Principal Recipient (PR) is the Ministry of Finance with MoHSW, National AIDS Commission, and NDSO as subrecipients. The Local Funding Agent is PricewaterhouseCoopers in South Africa.

The GFATM supports all the districts of Lesotho.

To date, the funding levels have been—

1. Phase I: 2004-5, USD 10.1 million (prevention, care and treatment, and governance)

2. Phase II: 2006-present, USD 34 million (USD 29 million for HIV and USD 5 million for TB); round 2 is for procurement of ARVs, OIs, STIs, and reagents
3. Round 5 is for USD 40 million over 5 years for health systems strengthening and includes provision of rapid test kits; the TB component includes procurement of laboratory commodities and training.

4. Applications were due in for Round 7, which focuses on orphans and vulnerable children and PMTCT. GFATM provides 30 percent of the national need for ARVs and laboratory reagents.

The GFATM funds support 68 sites for both GOL and CHAL. The GFATM Coordinating Unit’s main role is to coordinate MoHSW activities funded by GFATM and to monitor progress of work plans and fiscal activities.

Success of the GFATM program in meeting its goals and providing services is monitored and measured through the use of checklists, filed visit reports, and programmatic and financial audits. Quarterly and biannual reports are produced and are available on the GFATM website.

Scaling up of HIV&AIDS activities by the GFATM will be in response to government plans to scale-up.

The GFATM Coordinating Unit’s activities in supporting the supply chain include—

1. Policy development through advocating decentralizing procurement to line ministries.

2. Program management through the awarding of 26 subgrants to local NGOs.

3. Procurement and/or distribution through providing funds for procurement. This involves various vendors, but all distribution is done through NDSO.

4. Technical assistance to other organizations in the country through the provision of secretarial services to the Country Coordinating Mechanism, which meets on a monthly basis. One consultant who is supported by GFATM is based at NDSO.

5. Participation in the two Procurement Committees at the MoHSW: the PSM Committee and the Decentralization Committee.

The Clinton Foundation

The Clinton Foundation is headed by a Country Coordinator. With a staff complement of ten, the unit has program point persons for each supply chain area, e.g., Procurement and Supply Chain Management, Pediatrics, Laboratory, Human Resources.

The Foundation’s funding levels for country support between 2005 and 2010 were estimated at five million euros. Funding is provided through the Foundation’s own private sources as well as the UNITAID for pediatrics. The Clinton Foundation works in partnership with MoHSW and the Irish Aid.
The Foundation’s main role in providing antiretroviral and laboratory services in Lesotho is to set up an effective procurement and laboratory services team/committee to quantify, forecast, and order (placed twice a year now) supplies, to review and modify procurement systems, and to tender processes with NDSO and the Ministry of Health’s Procurement Unit. The Foundation uses MoHSW indicators and produces quarterly reports for submission to its headquarters.

The Clinton Foundation supports the following—

1. Policy development through their involvement in revising procurement guidelines and having FDC medicines for children approved for use.

2. Program management through coordination with HAHPCO for quantification and NDSO for distribution.

3. Human resource development through support for the advertising of the Procurement and Logistics Officer post for MoHSW, and funding for short-to-medium term positions at MoHSW (6 months–2 years). An example is their funding of HAHPCO staff for a period of two years.

4. Procurement of ARVs which is provided by their India office, ensuring access to cost effective medicines.

5. Negotiation of leasing deals for laboratory equipment and provision of transportation for samples.

6. Clinical services through providing a clinical mentoring program.

**Coordination of Efforts**

There is no doubt that the involvement of these and other partners increases funding levels and the types and numbers of international organizations on the ground, giving much-needed support to the national HIV&AIDS program. The assessment established the following—

- The development partners were not necessarily organized into a common body or forum that could coordinate funding activities or pool resources into one fund to disburse funds on behalf of all the partners and in a manner that would ensure accountability and transparency

- Several committees had been formed for specific supply chain functions or programs, for example the GFATM Procurement Committee, the Family Health Technical Advisory Committee, and the Technical Working Group on PMTCT

- Coordination and communication between government departments and donors was neither streamlined nor consistent, and it was not clear to all the MoHSW officials whose
Role of Developmental Partners in the Lesotho Supply Chain

responsibility it was to coordinate activities with donors and other developmental partners

- Some significant supply chain players are not involved with coordination efforts at the national level and tend to deal directly with facilities on the ground

- As a result of all of the above, the extent of duplications of effort or gaps could not be determined, as there was simply no structure in the system that allowed for any coordinated monitoring of partner activities

The lack of effective coordination of different activities being carried out by the various partners thus remains a big challenge.

Recommendations

- The results of this study, particularly in as far as they relate to the role of the donor community, should be circulated among the development partners, and further interviews conducted with significant supply chain management partners such as Irish AID, the Clinton Foundation, MSF, World Bank, and the Millennium Challenge Corporation

- The MoHSW should clearly define and communicate its central mandate for coordination of national supply chain management activities

- One option for the coordination of supply chain management activities would be the formation of a logistics subcommittee for all HIV/AIDS and laboratory-related commodities, with clear terms of reference

- The Directorate of Health Planning and Statistics should consider the establishment of an active donor coordination desk which would be visible to all partners and have sufficient authority within the MoHSW.vii

Thus, the major recommendation in this respect is for the partners and the MoHSW to work towards improved donor coordination. One way forward could be for a study to be carried out of donor activity organizations and coordination as it has been practiced and has evolved over the years in Mozambique via the Sector-wide Approach (SWAp) for health established in 2000. To many, the Health SWAp in Mozambique epitomized all the advantages of working sector-wide—improved government leadership, greater sector policy and strategic focus, more effective use of aid to the health sector, and lower transaction costs. It was an open, inclusive arrangement whereby the MOH and its development partners could share a set of common principles, objectives, and working arrangements.

vii As the report was being finalized, it was reported that a Donations Committee had been established within the MoHSW, which includes most of the health programs.
It has to be conceded that such an arrangement does have its own complexities which could have, unless carefully guided and treated with circumspection by the government of the country, counter-productive consequences as far as governance and self-determination are concerned.

Another model can be found in Zimbabwe where the Ministry of Health and Child Welfare (MoHCW) strongly emphasized supply chain management. The AIDS and TB Unit created a specific team just to manage the supply of HIV/AIDS-related commodities called the logistics subunit (LSU). The LSU consisted of 12 staff members whose sole function was to ensure the uninterrupted supply of HIV and AIDS-related commodities nationwide. Physically located on the premises of the national medical stores, NatPharm, the LSU coordinated closely with all partners and government departments. The LSU was given the mandate by the AIDS and TB Coordinator to play a key role in coordination, as a result of which there had been no nationwide stock-outs of essential HIV/AIDS-related products.

The main caveat to this approach is that the PEPFAR team provided significant support being provided by. The staff were JSI employees who were officially seconded to the MoHSW. Their transportation and office needs such as computers, printers, etc., were also provided by JSI. Obviously, the transfer of such lessons from country to country would need to take into account each country’s own unique circumstances.
PROPOSED MSH/SPS SUPPORT ACTIVITIES FOR THE PHARMACEUTICAL AND LABORATORY SECTORS

One of the deliverables given by the PEPFAR team in Lesotho to the assessment team was the development of a supply chain analysis.

“HIV/AIDS supply chain situation analysis report including short, medium and long term recommendations to be considered by in-country partners and donors, taking into account (1) the severe crisis in human resources for health that currently exists in Lesotho and (2) the multiplicity of partners that is currently involved in procurement and supply chain systems.”

It was the assessment team’s understanding that this report was not meant to be an academic exercise,—with a report being produced and presented to the MoHSW and left to gather dust on the shelves, only to be quoted in similar exercises in the future.

The team was encouraged by the PEPFAR team to explore innovative ways of resolving the problems encountered in Lesotho’s battle to make ARVs and laboratory commodities available to all the communities of the country where and when they are needed, in the required quantities and of a quality that is of a universally acceptable standard.

In fact, the deliverable quoted above explicitly calls for recommendations to be presented that could be considered for adoption by the in-country partners and donors. SPS, for its part, has identified a number of activities, some continuing from the previous financial year, others new and resulting directly from the findings of the assessment, that have now been incorporated into its Lesotho Country Operational Plan for 2009 (COP 2009).

Following is a summary of the activities that will be undertaken by SPS in the pharmaceutical and laboratory sectors. The detailed COP 2009 is available on request.

Proposed Support Activities for the Pharmaceutical Sector

The Rational Pharmaceutical Management (RPM) Plus Program managed by Management Sciences for Health (MSH) comes to an end in September 2008. However, MSH has been awarded the Strengthening Pharmaceutical Systems (SPS) program, the RPM Plus follow-on, which continues to focus on strengthening the delivery of pharmaceutical services at all levels, throughout Lesotho.

SPS will continue to engage in activities that aim to strengthen access not only to ARVs but to all commodities used to support other programs such as PMTCT, palliative care, TB/HIV, and laboratory services. In furtherance of a commitment made in 2007, SPS will also take over a significant amount of the support activities that had been initiated by Health Research for Action (HERA) under their World Bank-funded contract. This includes implementing SOPs in the
facilities and the training and supervision of pharmacists and pharmacy technicians in medicines supply management.

The activities will be carried out with the support and collaboration of the Pharmaceutical Directorate of the MoHSW. Regular feedback meetings will be convened with the directorate and with the NDSO, which will also be expected to become involved in the strengthening of procurement activities at the facility level.

Through SPS, MSH will continue to support the following areas—

- Review of existing pharmaceutical regulation and legislation;
- Establishment of the planned medicines regulatory authority and related training of its staff and officials;
- Training of health personnel (with focus on pharmacy personnel) and provide technical assistance in drug (and other commodities) supply management, quantification of requirements, HIV and AIDS management, TB management, pharmacy therapeutics committee, and infection control
- Review of the national essential drugs list and STGs
- Monitoring and evaluation of the availability of essential commodities
- Implementation of computerized and manual systems at NDSO and health facilities

Proposed Support Activities for the Laboratory Sector

It is envisaged that most of the activities described below will commence in the middle of financial year 2009—PEPFAR funding has already been applied for. However, training in areas such as the use of stock cards and quantification of requirements would commence as soon as additional staff members have been added to the SPS Lesotho team.

In the main, the activities in this sector can be summarized as follows—

- Seek collaboration with all other partners that are currently providing or may have provided support to the laboratory services in recent years and propagate for the formation of a laboratory coordinating committee;
- Appoint a full-time laboratory commodity management specialist in Lesotho to oversee all laboratory commodity management support activities and build capacity both centrally (NDSO central laboratory) and at individual health facilities.
- Train laboratory staff in all laboratories and the blood transfusion center in the use of stock cards, quarterly stock taking, and quarterly logistics reports; and provide on-site monitoring of implementation of these procedures.

- Assist laboratory staff to organize store rooms and refrigerated storage in individual laboratories.

- Facilitate the MoHSW to develop the national standard list of essential laboratory commodities required to carry out the tests needed at each level of the health system to support the basic healthcare package.

- Use the national list of essential laboratory commodities to assist with the development and dissemination of a national laboratory stores catalogue (including VEN classification).

- Develop a national laboratory inventory management system based on consumption data which provides for national quantification required for procurement, and quantification to identify how much to distribute to each individual laboratory. This will include the identification and adaptation of existing software currently used for drugs, staff training in the use of this software, and ongoing assistance with implementation of the software.

- Institute a monitoring and evaluation system for commodity management (checks and balances and audit), train staff in its use, and provide ongoing support.

- Provide ongoing support in laboratory logistics management, tendering, and procurement.
REFERENCES

1 UNFPA Situation Analysis of Reproductive Health Commodity Security in Lesotho, July 2007


